April 10, 2015

ENGROSSED
HOUSE BILL No. 1449

DIGEST OF HB 1449 (Updated April 8, 2015 1:17 pm - DI 104)

Citations Affected: IC 12-15; IC 12-23.

Synopsis: Opioid treatment. Limits Medicaid reimbursement for Subutex and Suboxone or an similar trade name or generic of the drug when the drug was prescribed for the treatment of pain management to only if the drug was prescribed by a physician who meets certain requirements. Allows for the office of Medicaid policy and planning to require prior authorization for these drugs when being prescribed for

(Continued next page)

Effective: July 1, 2015.

Davisson, Brown C, Brown T, Bacon

(SENATE SPONSORS — HERSHMAN, GROOMS, MILLER PATRICIA, STOOPS)

January 14, 2015, read first time and referred to Committee on Public Health.
February 5, 2015, reported — Do Pass.
February 9, 2015, read second time, ordered engrossed. Engrossed.
February 10, 2015, read third time, passed. Yeas 94, nays 0.

SENATE ACTION

February 24, 2015, read first time and referred to Committee on Health & Provider Services.
April 9, 2015, amended, reported favorably — Do Pass.

substance abuse treatment as determined by the board or when being prescribed for more than six months. Authorizes the division of mental health and addiction (division) to approve before June 30, 2018, not more than five new opioid treatment programs if: (1) the programs are run by a hospital or a certified community mental health center; and (2) the division determines that there is a need for a new opioid treatment program in the proposed location. Requires the division to report to the general assembly before July 1, 2018, specified information concerning any new facilities. Requires the division of mental health and addiction to adopt rules concerning: (1) opioid treatment by an opioid treatment provider; (2) take home opioid treatment medications; (3) clinical standards for tapering of a patient, relapse, and overdose prevention; and (4) specified standards and protocols for an opioid treatment provider. Requires an opioid treatment provider to periodically and randomly test a patient for specified drugs during treatment.

April 10, 2015

First Regular Session of the 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

ENGROSSED
HOUSE BILL No. 1449

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 35. (a) **Except as provided in IC 12-15-35.5-9,** before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 2. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS

[EFFECTIVE JULY 1, 2015]: **Sec. 9. (a) The office may not reimburse under Medicaid for Subutex, Suboxone, or a similar trade name or generic of the drug if the drug was prescribed for the treatment of pain or pain management, unless the prescriber is a physician licensed under IC 25-22.5 who:**

(1) has obtained a waiver from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and meets the qualifying standards required to treat opioid addicted patients in an office-based setting; and

(2) has a valid federal Drug Enforcement Administration registration number and a Drug Enforcement Administration identification number that specifically authorizes treatment in an office-based setting.

(b) The following apply to a prescription drug described in subsection (a) for a Medicaid recipient if the prescription is for the treatment of substance abuse:

(1) Prior authorization may be required for a prescription drug described in subsection (a):

(A) when the prescription drug is prescribed for more than six (6) months; or

(B) as determined by the board.

(2) The office may reimburse for the prescription drug for more than six (6) months for a Medicaid recipient only if:

(A) the drug is prescribed for the treatment of substance abuse; and

(B) the prescriber:

(i) is treating as part of an opioid treatment program approved and certified under and meets the requirements of IC 12-23-18; or

(ii) meets the requirements of IC 12-23-19.

SECTION 3. IC 12-23-18-5.5, AS AMENDED BY P.L.116-2008, SECTION 9, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 5.5. **(a)** The division may not grant specific approval to be a new opioid treatment program. This section does not apply to applications for new opioid treatment programs:

(1) pending prior to March 1, 2007; **or**

(2) that are operated by a hospital licensed under IC 16-21 or a certified community mental health center:

(A) within the licensed hospital or the center; or

(B) in a separate office that meets federal opioid treatment program requirements;

and that meets the requirements of this section.

(b) A hospital licensed under IC 16-21 or a certified community mental health center may apply to the division to operate an opioid treatment program. Upon approval, the hospital or community mental health center may operate an opioid treatment program in compliance with this chapter and federal law.

(c) Before June 30, 2018, the division may approve the operation of not more than five (5) additional opioid treatment programs described in subsection (a)(2) only if the division determines as described in subsection (e) that there is a need for a new opioid treatment program in the proposed location and the requirements of this chapter are met.

(d) Not later than June 30, 2018, the division shall report to the general assembly in an electronic format under IC 5-14-6 concerning whether any new opioid treatment programs have been approved under subsection (c). The report must include the following:

(1) The impact on access to opioid treatment programs.

(2) The number of individuals served in the opioid treatment programs approved under subsection (c).

(3) Treatment outcomes for individuals receiving services in the opioid treatment programs approved under subsection (c).

(4) Any recommendations the division has concerning future treatment programs.

(e) The division shall adopt rules under IC 4-22-2 setting forth the manner in which the division will determine whether there is a need for a new opioid treatment program in a proposed program location's geographic area.

SECTION 4. IC 12-23-19 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 19. Opioid Treatment Providers

Sec. 1. Subject to federal law and consistent with standard medical practices in opioid treatment for substance abuse, the division shall adopt rules under IC 4-22-2 concerning opioid treatment by an opioid treatment provider.

Sec. 2. (a) An opioid treatment provider shall periodically and randomly test, including before receiving treatment, a patient for the following during the patient's treatment by the provider:

(1) Methadone.

(2) Cocaine.

(3) Opiates.

(4) Amphetamines.

(5) Barbiturates.

(6) Tetrahydrocannabinol.

(7) Benzodiazepines.

(8) Any other suspected or known drug that may have been abused by the patient.

(b) If a patient tests positive under a test described in subsection (a) for:

(1) a controlled substance other than a drug for which the patient has a prescription or that is part of the patient's treatment plan with the provider; or

(2) an illegal drug other than the drug that is part of the patient's treatment plan with the provider;

the opioid treatment provider and the patient shall review the treatment plan and consider changes with the goal of opioid abstinence.

Sec. 3. The division shall adopt rules under IC 4-22-2 to establish the following:

(1) A requirement that an opioid treatment provider has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(2) Clinical standards for:

(A) the appropriate tapering of a patient on and off an opioid treatment medication;

(B) relapse; and

(C) overdose prevention.

(3) Standards and protocols for an opioid treatment provider to do the following:

(A) Assess new opioid treatment patients to determine the most effective opioid treatment medications to start the patient's opioid treatment.

(B) Ensure that each patient voluntarily chooses maintenance treatment and that relevant facts concerning the use of opioid treatment medications, including nonaddictive medication options, are clearly and adequately explained to the patient.

(C) Have appropriate opioid treatment patients who are receiving methadone for opioid treatment move to receiving other approved opioid treatment medications.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1449, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill do pass.

(Reference is to HB 1449 as introduced.)

CLERE

Committee Vote: Yeas 13, Nays 0

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1449, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 35. (a) **Except as provided in IC 12-15-35.5-9,** before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board

meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 2. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 9. (a) The office may not reimburse under Medicaid for Subutex, Suboxone, or a similar trade name or generic of the drug if the drug was prescribed for the treatment of pain or pain management, unless the prescriber is a physician licensed under IC 25-22.5 who:**

(1) has obtained a waiver from the federal Substance Abuse

and Mental Health Services Administration (SAMHSA) and meets the qualifying standards required to treat opioid addicted patients in an office-based setting; and

(2) has a valid federal Drug Enforcement Administration registration number and a Drug Enforcement Administration identification number that specifically authorizes treatment in an office-based setting.

(b) The following apply to a prescription drug described in subsection (a) for a Medicaid recipient if the prescription is for the treatment of substance abuse:

(1) Prior authorization may be required for a prescription drug described in subsection (a):

(A) when the prescription drug is prescribed for more than six (6) months; or

(B) as determined by the board.

(2) The office may reimburse for the prescription drug for more than six (6) months for a Medicaid recipient only if:

(A) the drug is prescribed for the treatment of substance abuse; and

(B) the prescriber:

(i) is treating as part of an opioid treatment program approved and certified under and meets the requirements of IC 12-23-18; or

(ii) meets the requirements of IC 12-23-19.".

Page 1, delete lines 7 through 15, begin a new line block indented and insert:

"**(2) that are operated by a hospital licensed under IC 16-21 or a certified community mental health center:**

(A) within the licensed hospital or the center; or

(B) in a separate office that meets federal opioid treatment program requirements;

and that meets the requirements of this section.

(b) A hospital licensed under IC 16-21 or a certified community mental health center may apply to the division to operate an opioid treatment program. Upon approval, the hospital or community mental health center may operate an opioid treatment program in compliance with this chapter and federal law.

(c) Before June 30, 2018, the division may approve the operation of not more than five (5) additional opioid treatment programs described in subsection (a)(2) only if the division determines as described in subsection (e) that there is a need for a new opioid treatment program in the proposed location and the requirements

of this chapter are met.

(d) Not later than June 30, 2018, the division shall report to the general assembly in an electronic format under IC 5-14-6 concerning whether any new opioid treatment programs have been approved under subsection (c). The report must include the following:

(1) The impact on access to opioid treatment programs.

(2) The number of individuals served in the opioid treatment programs approved under subsection (c).

(3) Treatment outcomes for individuals receiving services in the opioid treatment programs approved under subsection (c).

(4) Any recommendations the division has concerning future treatment programs.

(e) The division shall adopt rules under IC 4-22-2 setting forth the manner in which the division will determine whether there is a need for a new opioid treatment program in a proposed program location's geographic area.

SECTION 4. IC 12-23-19 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 19. Opioid Treatment Providers

Sec. 1. Subject to federal law and consistent with standard medical practices in opioid treatment for substance abuse, the division shall adopt rules under IC 4-22-2 concerning opioid treatment by an opioid treatment provider.

Sec. 2. (a) An opioid treatment provider shall periodically and randomly test, including before receiving treatment, a patient for the following during the patient's treatment by the provider:

(1) Methadone.

(2) Cocaine.

(3) Opiates.

(4) Amphetamines.

(5) Barbiturates.

(6) Tetrahydrocannabinol.

(7) Benzodiazepines.

(8) Any other suspected or known drug that may have been abused by the patient.

(b) If a patient tests positive under a test described in subsection (a) for:

(1) a controlled substance other than a drug for which the patient has a prescription or that is part of the patient's treatment plan with the provider; or

(2) an illegal drug other than the drug that is part of the patient's treatment plan with the provider;

the opioid treatment provider and the patient shall review the treatment plan and consider changes with the goal of opioid abstinence.

Sec. 3. The division shall adopt rules under IC 4-22-2 to establish the following:

(1) A requirement that an opioid treatment provider has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(2) Clinical standards for:

(A) the appropriate tapering of a patient on and off an opioid treatment medication;

(B) relapse; and

(C) overdose prevention.

(3) Standards and protocols for an opioid treatment provider to do the following:

(A) Assess new opioid treatment patients to determine the most effective opioid treatment medications to start the patient's opioid treatment.

(B) Ensure that each patient voluntarily chooses maintenance treatment and that relevant facts concerning the use of opioid treatment medications, including nonaddictive medication options, are clearly and adequately explained to the patient.

(C) Have appropriate opioid treatment patients who are receiving methadone for opioid treatment move to receiving other approved opioid treatment medications.".

Delete page 2.

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to HB 1449 as printed February 6, 2015.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 7, Nays 0.